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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/623,238      | 07/17/2003  | Edward Lynch         | 3068                | 2886             |

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EXAMINER

KRASS, FREDERICK F

ART UNIT PAPER NUMBER

1614

DATE MAILED: 10/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                                       |                                     |  |
|------------------------------|---------------------------------------|-------------------------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/623,238  | <b>Applicant(s)</b><br>LYNCH ET AL. |  |
|                              | <b>Examiner</b><br>Frederick F. Krass | <b>Art Unit</b><br>1614             |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --.

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-5 and 10-27 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 10-27 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |  |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)            |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>07/17/2003</u> . | 6) <input type="checkbox"/> Other: ____  |

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### **Specification**

1) Applicant is requested to amend the first lines of the specification to 1) update the reference to priority to USSN 10/096,050 (i.e., Applicant should state that this application is now USP 6,649,148), and 2) make reference to the claim to priority to 60/279,795.

2) The use of trademarks has been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Examples include those used at p. 7, i.e. "OptiBond", "OptiGuard" and "ChemFil" products. Those trademarks (as well as all others as appropriate as they appear throughout the specification) should be capitalized, e.g. "OPTIBOND FL PRIME".

### **Claim Informalities**

The following informalities are noted and should be corrected in responding to this Office action:

- i) claim 1, first line, the sixth word on the line is spelled incorrectly;
- ii) claim 4, tenth line of the claim, the second word on the line is spelled incorrectly;
- iii) claim 5, second line of the claim, "comprising" should be changed to "comprises";
- iv) claim 5, third to last line of the claim, the first word on the line is spelled incorrectly; and
- v) the recitation of zero parts sodium hydroxide at the penultimate line of claim 4, and FD&C Blue #1 at the penultimate line of claim 5, respectively, while not

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indefinite *per se*, is superfluous, and the claims would be in better form were those recitations removed. (Why recite a component which isn't even there?)

### **Indefiniteness Rejection**

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 4 and 5 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 4 and 5 contain the trademark/trade names "CMC-7MXF", "Sylodent 756", "Zeodant 165", "Noville AN114153", and "Tauranol WS HP", respectively.

Where a trademark or trade name is used in a claim as a limitation to identify or describe a particular material or product, the claim does not comply with the requirements of 35 U.S.C. 112, second paragraph. See *Ex parte Simpson*, 218 USPQ 1020 (Bd. App. 1982). The claim scope is uncertain since the trademark or trade name cannot be used properly to identify any particular material or product. A trademark or trade name is used to identify a source of goods, and not the goods themselves. Thus, a trademark or trade name does not identify or describe the goods associated with the trademark or trade name. In the present case, the trademark/trade names are used to identify/describe various components of remineralizing compositions and, accordingly, the identification/description is indefinite.

### **Obviousness Rejection**

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said

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subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary.

Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1) Claims 1-3 and 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (6,409,508) in view of Winston et al (USP 5,817,296).

The primary reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art only under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 103(a) might be overcome by: (1) a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not an invention "by another"; (2) a showing of a date of invention for the claimed subject matter of the application which corresponds to subject matter disclosed but not claimed in the reference, prior to the effective U.S. filing date of the reference under 37 CFR 1.131; or (3) an oath or declaration under 37 CFR 1.130 stating that the application and reference are currently owned by the same party and that the inventor named in the application is the prior inventor under 35 U.S.C. 104, together with a terminal disclaimer in accordance with 37 CFR 1.321(c). This rejection might also be overcome by showing that

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the reference is disqualified under 35 U.S.C. 103(c) as prior art in a rejection under 35 U.S.C. 103(a). See MPEP § 706.02(l)(1) and § 706.02(l)(2).

The primary reference discloses methods for treating dental caries comprising directing a jet of ozone onto carious lesions for a period of time sufficient to kill microorganisms within the carious lesion. The method is identical to that claimed instantly, prior to application of the remineralization formulation. See and compare, the instant claims with claims 1-28 of the patent. Accordingly, the primary reference differs from the instant claims insofar as it is silent regarding application of a remineralization agent following ozone treatment, although it does state at col. 2 (see line 14) that "a sealant of the type known in the art may be applied to a carious lesion following ozone treatment" (presumably in order to protect the treated lesion from subsequent damage due to reexposure to caries-inducing conditions).

The secondary reference discloses remineralizing compositions comprising calcium and phosphate salts and teaches that when a divalent metal salt, e.g., zinc chloride (col. 7, lines 49-56), is used to stabilize the compositions their efficacy in treating subsurface lesions is significantly improved (see the passage bridging col. 4, line 62 to col. 5, line 14). The secondary reference differs from the instant claims insofar as it is silent regarding the use of ozone.

It would have been obvious to have applied a composition comprising calcium, phosphate, and zinc salts to teeth following the ozone treatments of the primary reference, motivated by the desire to protect treated lesions from subsequent damage by strengthening tooth subsurfaces through remineralization as taught by the secondary reference.

2) Claims 1-3 and 10-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lynch (WO 99/64020) in view of Winston et al (USP 5,817,296).

The primary reference is substantially cumulative of USP 6,409,508, discussed in subsection "1)" supra. Accordingly, it would have been obvious to have applied a composition comprising calcium, phosphate, and zinc salts to teeth following the ozone treatments of the primary reference, motivated by the desire to protect treated lesions from subsequent damage by strengthening tooth subsurfaces through remineralization as taught by the secondary reference (also discussed in subsection "1)" supra).

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### **Obviousness-Type Double Patenting Rejection**

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-3 and 10-27 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-28 of U.S. Patent No. 6,409,508 in view of Winston et al (USP 5,817,296).

The conflicting patent is discussed in subsection "1)" of the "Obviousness" section supra, and as discussed therein, its claims differ from the instant claims insofar as they do not specify a remineralization step following ozone treatment. It would have been obvious to have applied a composition comprising calcium, phosphate, and zinc salts to teeth following the ozone treatments of the primary reference, motivated by the desire to protect treated lesions from subsequent damage by strengthening tooth subsurfaces through remineralization as taught by the secondary reference (also discussed in subsection "1)" supra).

### **Allowable Subject Matter**

Claims 4 and 5 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, 2nd paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

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The prior art does not fairly suggest, teach or disclose the specific remineralization formulations of the instant claims. (Those compositions are in fact the subject of the claims of USP 6,669,931).

#### **Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick F. Krass whose telephone number is 571-272-0580. The examiner's schedule is 9:30AM – 6:00PM, Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached at 571-272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
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